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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Andrés RIVERA et al.

Group Art Unit: 1772

Application No.: 09/353,592

Examiner: S. Hon

Filed: July 15, 1999

Docket No.: 101054

For: APPLICATOR FOR A POLYMERIZABLE MONOMER

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Scott Keplinger, a citizen of the United States, hereby declare and state:

1. I have a Bachelor of Science degree in Biology, which was conferred upon me by North Carolina Central University in Durham, North Carolina in 1997.
2. I have been employed by Closure Medical Corporation since 1995 and I have had a total of 6 years of work and research experience in cyanoacrylate adhesive technology.
3. I and/or those under my direct supervision and control have conducted the following experiments:
4. Two boxes of DERMABOND® Topical Skin Adhesive applicators were obtained, with the boxes from separate production lots denoted Lot A and Lot B. Each box contained twelve adhesive applicators. Samples from separate lots were used to minimize any lot-related variation.

From each box, six adhesive applicators were removed. The adhesive applicators were cut open to remove the glass ampoules containing the cyanoacrylate adhesive formulation, and the applicator tips containing the initiator were discarded. The glass ampoules containing the cyanoacrylate adhesive formulation were dipped into a 10% solution of benzalkonium chloride (initiator) in acetone (solvent), and were then removed and dried. This resulted in depositing the benzalkonium chloride initiator on the outer surface of the glass ampoule, in the manner claimed in the above-identified patent application. The coated ampoules were then placed into butyrate tubes and the tubes were sealed with POREX® applicator tips (similar to the original butyrate tubes and applicator tips), except that the applicator tips did not include initiator therein.

The remaining six adhesive applicators from each lot were used as supplied. These applicators thus included applicator tips having an amount of benzalkonium chloride initiator disposed in the applicator tip.

5. For each of the resultant 24 adhesive applicators, testing was conducted to determine the setting time of successive droplets of adhesive expressed through the applicator tip. The setting time measurement is used to determine the efficiency of the initiator in initiating polymerization of the adhesive, and helps to determine whether the initiator provides its desired result (initiation) throughout use of the applicator, i.e., from a first drop to a last drop when all of the adhesive is used.

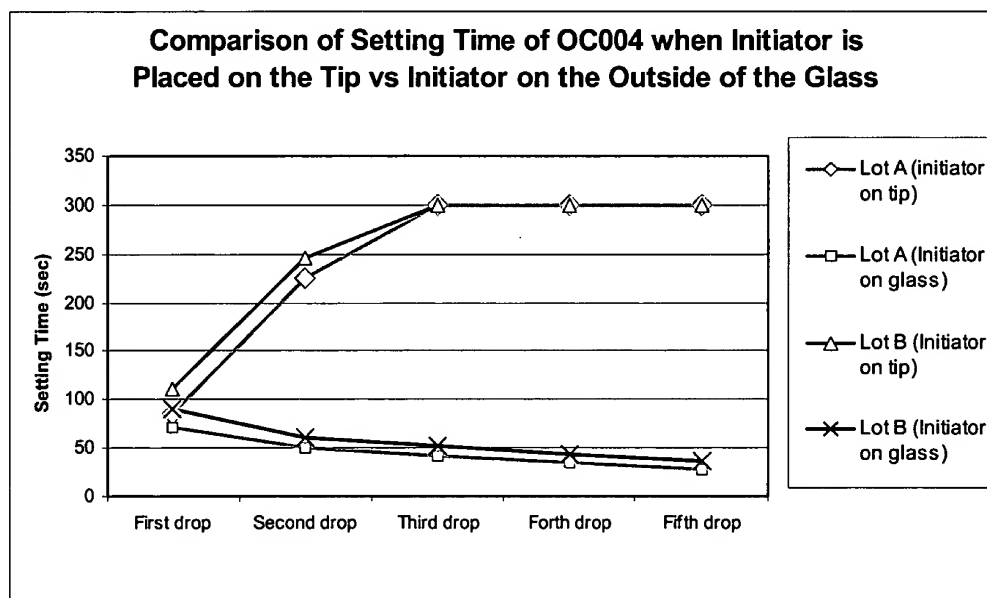
The test was conducted by activating the applicator according to the instructions provided with the applicators. That is, the butyrate tube was squeezed to rupture the enclosed glass ampoule. The applicator was then inverted (applicator tip down), and the adhesive was squeezed through the applicator tip. A first drop of adhesive was formed on the applicator tip and allowed to drop onto a test surface. A timer was immediately started to determine the setting time of the drop. Once the timer was started, the applicator was moved to a

subsequent test surface, a second drop of adhesive was formed and dropped onto the test surface, and a second timer was started. This procedure was repeated for up to five drops, which exhausted the adhesive supply in the applicators. The results of the testing are shown in the following table:

Lot	Initiator Location	Average Setting Time (sec)				
		1 st Drop	2 nd Drop	3 rd Drop	4 th Drop	5 th Drop
A	In Tip	85	225	300+	300+	300+
A	On Ampoule	71	51	42	34	27
B	In Tip	111	245	300+	300+	300+
B	On Ampoule	90	61	52	44	36

NOTE: A time of "300+" indicates that the drop did not set.

Graphically, a plot of the average setting time versus expressed drop is shown as follows:



6. The above data and chart clearly demonstrate unexpected results of the claimed invention. The experiment demonstrates that placement of the initiator with respect to the contained adhesive can have significant effects on the setting characteristics of the adhesive. The experiment demonstrates that although the setting time of the first drop

expressed through the applicator tip appears to be independent of the initiator location, the results drastically diverge as successive drops are expressed through the applicator tip. That is, for second and subsequent drops, inferior setting results are obtained even for the second drop, when the initiator is placed in the applicator tip rather than on the outer surface of the glass ampoule. For the third, fourth and fifth (final) drops, the results are even worse -- setting did not occur, even after 300 seconds. In contrast, when the initiator is coated on the outer surface of the glass ampoule, setting characteristics of the adhesive remain acceptable, with all drops setting in 90 seconds or less.

7. As a further experiment, it was attempted to reproduce the above experiment, but to prepare applicators where the initiator is coated on the inner surface of the outer container (butyrate tube). However, such applicators could not be prepared. To apply the initiator to the applicator tube, it is dispersed in a solvent such as acetone or ethyl alcohol. However, the solvents interact with the butyrate, causing the tube to deform and become unusable. Accordingly, the experiment was discontinued.

8. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefore.

Date:

9/3/2003

Scott Keplinger